

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 20 and 21 were pending in this application when last examined and stand rejected.

Claims 20 and 21 have been amended to clarify that in the enzyme immunoassay chip, a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part so as to produce an increased signal strength. Support can be found at page 5, lines 6-12 and page 7, line 20 to page 8, line 6.

Claim 21 has been amended to clarify that the claimed invention involves “antigen-antibody” reactions. Support can be found at page 3, lines 1-9, and page 7, lines 5-6 and line 25.

Claims 20 and 21 were amended to correct a grammatical error by amending the claims to recite “an inlet” instead of “a inlet.” Support can be found in the claims as filed.

Therefore, no new matter has been added by this amendment.

II. INDEFINITENESS REJECTION

In item 4 on page 2 of the Action, claim 21 was rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the term “antigen antibody.”

This rejection is respectfully traversed as applied to the amended claim.

Claim 21 has been amended to clarify that the claimed invention involves “antigen-antibody” reactions.

The specification, at page 3, lines 1-9, describes the claimed enzyme immunoassay, whereby antigen-antibody reactions with an enzyme occur in the flow passage part. Example 1, at page 7, lines 5-6 and line 25, provides an example of an “antigen-antibody reaction.” It is respectfully submitted that such language is conventional and well known in the art. Thus, the

indefiniteness rejection under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

III. PRIOR ART REJECTIONS

In item 7 on pages 3-4 of the Action, claim 20 was rejected under 35 U.S.C. § 102(e) as anticipated by Harrison (US 6,432,290).

In item 11 on pages 5-7, claim 21 was rejected under 35 U.S.C. § 103(a) as obvious over Harrison in view of Eteshola (Sensors and Actuators B, vol. 72, pp. 129-133 (2001)) and Sato (Analytical Sciences, vol. 15, pp. 525-529 (1999)).

These rejections are respectfully traversed as applied to the amended claims. Since Harrison is the primary reference in each rejection, the rejections will be addressed together below.

In item 12 on pages 8-10 of the Action, it was indicated that the prior art rejections were maintained on the basis that: (1) contrary to Applicants' arguments, Harrison does teach "a reaction flow passage part which consists of an inlet part for bead-bodies with antibodies fixed thereon"; and (2) Applicants are arguing limitations not in the claims with regard to the bead-bodies contributing to signal strength and the majority of fluorescent reagents reaching the detector. See, for instance, the 2nd paragraph on page 9 of the Action.

In reply, the claims have been amended to clarify that in the enzyme immunoassay chip, a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part so as to produce increased signal strength.

Specifically, amended claim 20 calls for an enzyme immunoassay chip comprising a micro channel, which comprises a reaction liquid leading-in flow passage part, a reaction flow passage part and a detection flow passage part, which are successively connected with each other on a substrate. The reaction flow passage part consists of an inlet part for bead-bodies with

antibodies fixed thereon, a flow stopping part for stopping the flow of the bead-bodies through the reaction flow passage part and an area between the inlet part for the bead-bodies and the flow stopping part. The flow stopping part has a channel depth that is shallower than that of the reaction flow passage part to thereby stop the flow of bead-bodies through the reaction flow passage part. More importantly, in the enzyme immunoassay chip of the amended claims, a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part so as to produce increased signal strength.

Amended claim 21 is directed to a method of using the enzyme immunoassay chip.

It is again respectfully submitted that Harrison fails to disclose or suggest a reaction flow passage part which consists of a inlet part for bead-bodies with antibodies fixed thereon, a flow stopping part for the bead-bodies and an area between the inlet part for the bead-bodies and the flow stopping part. Moreover, Harrison fails to an enzyme immunoassay chip wherein a majority of enzyme reaction products produced by antigen-antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part so as to produce increased signal strength.

Harrison could not teach the specific structure and function of a reaction flow passage part which consists of a inlet part for bead-bodies with antibodies fixed thereon, a flow stopping part for the bead-bodies and an area between the inlet part for the bead-bodies and the flow stopping part, whereby the enzyme immunoassay chip is capable of producing an increased signal strength in which a majority of enzyme reaction products produced by antigen antibody reactions with an enzyme in the reaction flow passage part reach the detection flow passage part.

The micro-fluidic analysis system of Harrison comprises at least one pair of weirs (Ex. 6, 7 in Figs. 1A, 1B and 2A) formed across a main channel and at least one side channel (Ex. 5 in Fig. 1A, 1B and 2A) that is connected with the main channel between the weirs, which provides a higher resistance than the main channel.

In the micro- fluidic analysis system of Harrison, the solvent flow (as described in Fig. 2A) passes mainly along a cover plate, and it is not combined with a liquid in chamber (4) between the weirs. This structure differs from that of the claimed enzyme immunoassay chip. When the solvent flow in Harrison is moving at a high enough speed to cause agitation in chamber (4) between the weirs, a large volume of liquid flows into the reservoir (3) against the resistance of said side channel (5).

Furthermore, the micro-fluidic analysis system of Harrison (as described in Fig. 9) has trapping zones (25, 30 and 35) and each trapping zone is connected to side channels (24, 26, 29, 31, 35 and 36).

However, as described in column 17, line 66 to column 18, line 8 of Harrison, the elution solvent is provided from an upper stream side at the weir (6e), and is delivered to exit channel (37) or collection (4) at down stream side of the weir (6f).

Accordingly, the system of Fig. 9 is similar to the system of Fig. 2, and only provides a little part of a concentrated protein digest to the stage of final analysis.

Therefore, in the micro- fluidic analysis system of Harrison, the majority of beads (12) in the chamber (4) do not contribute to the increase of signal strength, as achieved by the present invention. Consequently, the system in Harrison cannot provide “the increased signal strength”, because the majority of elution of the fluorescent labeled reagent does not reach to detector (2). In other words, the bead-bodies in the micro- fluidic analysis system of Harrison do not contribute to signal strength, because the majority of beads do not reach the detector as in the present invention.

Thus, as noted in the last response, the invention in Harrison only adds to the technical problem in the prior art, which was eventually solved by the present invention (i.e., to “obtain a signal strength sufficient for the measurement”).

Furthermore, in the micro-fluidic analysis system of Harrison, the beads (12) are added to the chamber (4) between at least one pair of weirs (6 and 7) by a side channel (5), which is

connected with the chamber (4). In other words, the side channel (5), which is connected with the chamber (4), is indispensable, because it supplies beads to the chamber. Such structure is different from that of the present invention.

The secondary references of Eteshola and Sato fail to provide a suggestion to improve upon the structure of the micro channel in Harrison by cancelling the weir (6) at on an stream side in order to provide "the increased signal strength" as in the present invention.

Instead, Sato relates to a thermal-lens microscope to detect optical irradiation in a micro-fluidic channel. Eteshola relates to downstream detection of a fluorophore in a micro-fluidic device. As discussed above, neither reference provides a suggestion to modify the micro-fluidic device of Harrison to arrive at the claimed enzyme immunoassay chip.

Eteshola and Sato fail to disclose or suggest any means for providing increased signal strength or passing a majority of enzyme reaction products beyond the weir in the micro-fluidic analysis system of Harrison.

Also, with regard to claim 21, as noted at the top of page 8 of the Office Action of May 25, 2005, Harrison fails to disclose or suggest that the enzyme reaction product is produced by antigen antibody reaction with an enzyme.

The remaining cited references fail to remedy this deficiency in Harrison.

Therefore, Harrison and the combination of the secondary references of Eteshola, and Sato fail to teach or suggest each and every element of the claimed invention.

In view of the above, the anticipation rejection under 35 U.S.C. § 102(e) over Harrison and the obviousness under 35 U.S.C. § 103(a) over Harrison in view of Eteshola and Sato are untenable and should be withdrawn.

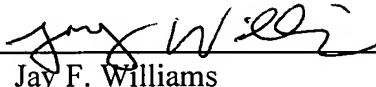
CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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